

## PATENT COOPERATION TREATY

PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY



(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 03 JAN 2006

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Applicant's or agent's file reference P61329WO00	<b>FOR FURTHER ACTION</b> See Form PCT/IPEA/416	
International application No. PCT/GB2004/002315	International filing date (day/month/year) 01.06.2004	Priority date (day/month/year) 16.10.2003
International Patent Classification (IPC) or national classification and IPC A61M15/00		
Applicant BESPAK PLC et al.		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 1 sheets, as follows:</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand  16.08.2005	Date of completion of this report  29.12.2005	
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Azaïzia, M  Telephone No. +49 89 2399-6960 	

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PCT/GB2004/002315

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-4, 6-25	as originally filed
5	received on 18.08.2005 with letter of 16.08.2005

**Claims, Numbers**

1-32	as originally filed
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**Drawings, Sheets**

1/11-11/11	as originally filed
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- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	11-14,17,18,22-29
	No: Claims	1-10,15,16,19,20,21,30-32
Inventive step (IS)	Yes: Claims	
	No: Claims	1-32
Industrial applicability (IA)	Yes: Claims	1-32
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

1. Reference is made to the following documents:  
D1: US-B1-6 390 088 (NOEHL KLAUS ET AL) 21 May 2002 (2002-05-21)  
D2: WO-A-95/07723 (MEDTRAC TECH INC) 23 March 1995 (1995-03-23)
2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

The document **D2** discloses (the references in parentheses applying to this document) a dispenser ("electronic inhalant device 100" shown in fig.1) comprising:

- a housing ("body housing 120"), a pressure sensor ("main sensing element 425" - see also page 9, lines 19-24, and page 15, line 36 to page 16, line 16 - fig. 4), processing means ("electronic assembly 400" shown in fig. 4) and a display means ("LCD 1135" shown in fig.11), the housing being shaped for receiving, in use, a dispensing container ("canister package 215" shown in fig.2) of the type containing medicament and having valve means for dispensing the medicament in metered volume doses, wherein, in use
- the pressure sensor ("main sensing element 425") is capable of detecting a pressure signature produced in dispensation of medicament from the dispensing container ("...pressure or piezo sensors detecting changes in pressure as medicated inhalant passes in the approximate path of sensor elements 425 and 435" - see also page 15, line 36 to page 16, line 16), wherein the pressure sensor is operatively connected to the processing means ("electronic assembly 400") for relaying signals indicative of the pressure signature for processing by the processing means (see page 16, line 25 to page 17, line 7 - fig.8),
- the processing means ("electronic assembly 400") being programmed to analyse said signals and compare said signals against one or more data sets containing data indicative of one or more control pressure signatures, the processing means being programmed to use the result of said comparison to detect the quantity of medicament dispensed compared to an intended volume of the metered dose volume (see also page 16, line 25 to page 17, line 12, and page 18, lines 7-33 - fig.8).

The subject-matter of independent claim 1 is therefore not new (Article 33(2) PCT).

The arguments of the applicant that the only embodiments disclosed in **D2** use a thermistor and that there is no clear teaching that any other form of sensing means may be used to produce the same effect as described in **D2** have been considered. Nevertheless, the document **D2** clearly disclosed the possibility of using pressure or piezo sensors for detecting changes in pressure as medicated inhalant passes in the approximate path of sensor elements 425 and 435 (see page 15, line 36 to page 16, line 16; see also page 9, lines 19-24).

3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 does not involve an inventive step (Article 33(3) PCT).

The document **D1** discloses (the references in parentheses applying to this document) a dispenser ("inhaler 1" shown in fig.1) comprising:

- a housing ("housing" - see c.5, l.64), a sensor ("first thermal sensor 5"), processing means ("electronic module 3") and a display means ("optical display unit 34"), the housing being shaped for receiving, in use, a dispensing container ("supply container 2") of the type containing medicament and having valve means for dispensing the medicament in metered volume doses, wherein, in use
- the sensor ("first thermal sensor 5") is capable of detecting a signature ("temperature profile" - see c. 3, l.4) produced in dispensation of medicament from the dispensing container (see c.1, l.64 to c.2, l.4), wherein the sensor ("first thermal sensor 5") is operatively connected to the processing means ("electronic module 3") for relaying signals indicative of the signature for processing by the processing means (see c.1, l.56 to l.63),
- the processing means ("electronic module 3") being programmed to analyse said signals and compare said signals against one or more data sets containing data indicative of one or more control signatures, the processing means being programmed to use the result of said comparison to detect the quantity of medicament dispensed compared to an intended volume of the metered dose volume (see c.2, l.40 to l.58).

The subject-matter of claim 1 therefore differs from this known dispenser in that the sensor is a pressure sensor capable of detecting a pressure signature produced on dispensation of medicament from the dispensing container. It is however generally

known to the person skilled in the art that a pressure sensor is an equivalent to the thermal sensor of document **D1** (see for example document **D2** - page 9, lines 19-24, and page 15, line 36 to page 16, line 16) and can be interchanged with that feature where circumstances make it desirable. Moreover, the pressure sensor of the present invention does not contribute to any particular technical problem which is not already solved by the thermal sensor of document **D1**. Consequently, the pressure sensor is merely one of several straight-forward possibilities from which the skilled person would select without the exercise of inventive skill (Article 33(3) PCT).

4. The additional features of dependent claims 2-32 are **EITHER** already known from the state of the art (see documents **D1-D2** and the corresponding passages cited in the search report), **OR** define slight constructional changes in the dispenser which come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, dependent claims 2-32 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step.
5. The subject-matter of claims 1-32 is considered industrially applicable since it can be made or used in any kind of industry (Article 33(4) PCT).

#### **Re Item VII**

##### **Certain defects in the international application (form and content)**

6. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents **D1** and **D2** is not mentioned in the description, nor are these documents identified therein.
7. The independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, with those features known in combination from the prior art (documents **D1** and/or **D2**) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
8. The features of the claims are not provided with reference signs placed in parentheses

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(Rule 6.2(b) PCT).

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An approximation of the accumulated quantity of product remaining in the dispensing container or dispensed therefrom may thus be made. As the amount of medicament dispensed is more accurately monitored, the dispensing container may be safely used nearer its exhaustion point.

The processing means may analyse one or more of the frequency, duration, area, rising slope, falling slope and amplitude of the pressure signature.

In one embodiment, the processing means applies a band-pass filter to the pressure signature.

The processing means may select a signature envelope for further signal processing.

The processing means may apply a notch filter to the pressure signature to slice the signature into discrete segments of equal time duration. The processing means may then compare the number of signal-containing segments with a control number derived from the one or more data sets.

In one embodiment the pressure sensor is an acoustic sensor and the pressure signature is an acoustic signature.

Alternatively, the pressure sensor is selected from the group consisting of a vibration sensor, a strain sensor, a compression sensor, a deflection sensor, and a ~~flex sensor~~.

The acoustic sensor may be a microphone. The microphone may a micro-electro-magnetic microphone.